

REMARKS

Claims 1-3, 6-7, and 10-19 are pending in the present application. No new matter is inserted into the application.

**Restriction Requirement**

The Examiner requires that Applicant make an election of species. Specifically, the Examiner states that Applicant must elect a single hydroximic acid derivative of the instant formula I. In response to the election of species requirement, Applicant elects O-(3-piperidino-2-hydroxy-1-propyl)-nicotinic amidoxime or a pharmaceutically acceptable acid addition salt thereof, represented by claim 2, with traverse. Reconsideration of the claims and withdrawal of the instant restriction are respectfully requested.

Applicant respectfully submits that the Examiner has issued an improper restriction/election requirement. As stated in MPEP § 803, "Examiners must provide reasons and/or examples to support conclusions..." U.S. Pat. & Trademark Off., Manual Pat. Examining Proc. § 803 (8<sup>th</sup> ed. rev. 1, 2003). In the present Office Action, the Examiner fails to make any statements whatsoever of the reasoning behind the restriction requirement. The Examiner merely states that the claims are generic to a

plurality of "patentably distinct" species. If only for this reason, Applicant submits that the restriction requirement is improper.

Furthermore, Applicant respectfully submits that the Examiner has failed to show a *prima facie* case of a serious burden in searching for all claims as required by MPEP § 803. As further stated in MPEP § 803, "[A] serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separated classification, separate status in the art, or a different field of search as defined in MPEP § 808.02." Again, the Examiner fails to provide Applicant with this information. The Examiner does not show by appropriate explanation the separate classification of the distinct inventions, nor the separate status in the art when they are classifiable together, and also does not mention the different fields of search. Further, the Examiner does not state or imply that searching for all of the claims will create an undue burden for the Examiner. Therefore, the present restriction requirement is not in accordance with MPEP §§ 808.02 (A), (B) and (C), since none of the above mentioned elements are mentioned.

Applicant submits that the search for the use of, and pharmaceutical composition comprising, combinations of hydroximic acid derivatives with known antitumor agents, would not cause *undue burden* to the Examiner. Since the specification defines clearly a class of compounds (hydroximic acid derivatives) which provides the desired properties to the antitumor composition, i.e. antitumor activity against tumors sensitive to the combination, the search field would be quite defined. Therefore, Applicant does not believe that the combinations claimed would create an undue search burden, and in this respect, a reconsideration of the restriction requirement is respectfully requested.

Additionally, it is also appropriate to mention that according to MPEP § 2165.01 (II) "there is no statutory requirement for the disclosure of a specific example (...)", and also to MPEP 2165.01 § (III) "there is no requirement in the statute that applicants point out which of their embodiments they consider to be their best (...)." U.S. Pat. & Trademark Off., Manual Pat. Examining Proc. § 2165.01 (8<sup>th</sup> ed. rev. 1, 2003). Therefore, if a class of compounds, i.e. hydroximic acids derivatives, is claimed, there would not be a statutory

necessity to elect only one of the possible hydroximic acid derivatives.

Although Applicant submits the above arguments, Applicant also presents the preferred hydroximic acid derivative in claim 2. This claim is directed to the pharmaceutical composition of claim 1, comprising O-(3-piperidino-2-hydroxy-1-propyl)-nicotinic amidoxime or a pharmaceutically acceptable acid addition salt thereof, as the hydroximic acid derivative. However, the present invention is not restricted to the preferred example, since this would be one of the preferred embodiments to carry out the invention, serving as a matter of example. The actual scope of the present invention comprises the pharmaceutical composition containing any of the claimed hydroximic acid derivatives with a known active substance having antitumor activity, wherein the antitumor activity is against tumors sensitive to the combination. A method for reducing side effect(s) in a patient requiring treatment for a tumor is also claimed.

For the above reasons, Applicant respectfully requests that the restriction requirement be withdrawn. An early and favorable action on the merits of the present application is earnestly solicited.

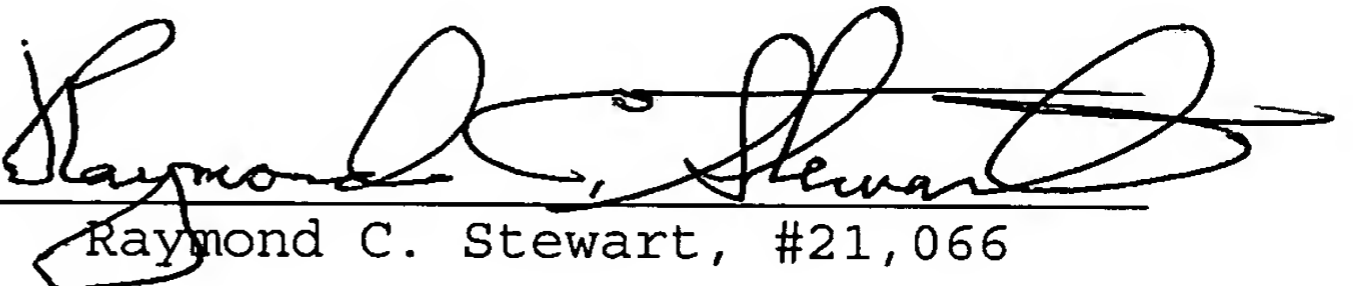
Application No. 10/084,095

If the Examiner has any questions concerning this application, the Examiner is requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees under 37 C.F.R. 1.16 or under 37 C.F.R. 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Raymond C. Stewart, #21,066

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000

*KLR*  
RCS/KLR  
1060-0144P